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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,783	12/08/2003	L. Dean Parks	1238.009	4821

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,783	PARKS, L. DEAN	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-16 are pending in the application.

Response to Arguments

1. Applicant's arguments filed 5/26/09 and 6/24/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearlman et al. (WO/9918800) in view of Huet et al. (US 6,426,333B1) as stated in the office action mailed 1/29/09.

4. Applicant asserts that Pearlman et al. teaches the ivermectin concentration from about 0.25% to about 2.5% to be effective.

5. The reference of Pearlman et al. was not used to teach of the ivermectin concentration of the instant claims but was used to teach of the combination of ivermectin and a pediculostatic agent (i.e. CETAPHIL ® cleanser).

6. Huet et al. was used to teach of the spot-on formulations comprising ivermectin in concentrations of 0.1%, 0.25%, etc.

7. Applicant asserts that Pearlman et al. further teaches away from applicant's claimed composition as it teaches of the use of Cetaphil ® Cleanser as a pediculostatic agent and ivermectin as a pediculocide. It is important to understand that Cetaphil ® Cleanser is a distinctly different product and has a distinctly different composition from Cetaphil ® moisturizing lotion. All of the examples of Pearlman et al. demonstrate their invention using Cetaphil ® Cleanser.

8. Pearlman et al. teaches that any commercially available product, such as cleansers, lotions, moisturizers, etc. may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion (Pearlman et al., p17, lines 1-10). Therefore it would have been obvious to one skilled in the art to substitute the Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers interchangeably as a pediculostatic agent.

9. Applicant asserts that Cetaphil ® moisturizing lotion is noncomedogenic and does not contain fragrance, lanolins or parabens that could irritate sensitive skin. However, for the purpose of cleansing Cetaphil ® Cleanser contains chemicals that are not suitable for the moisturizing lotion, for example, sodium lauryl sulfate and three different parabens.

10. Pearlman et al. teaches that any commercially available product, such as cleansers, lotions, moisturizers, etc. may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion (Pearlman et al., p17, lines 1-10). Therefore it would have been obvious to one skilled in the art to substitute the Cetaphil ®

moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers interchangeably as a pediculostatic agent.

11. Applicant asserts that Huet et al. teaches that a spot-on formulation containing a 1-phenylpyrazole derivative and ivermectin in a liquid carrier and in a form, which exhibits a synergistic activity against parasites. The single formulation makes possible a single application or an application repeated a small number of times, will be administered to the animal over a highly localized region of the animal, and it has been discovered that such a formulation is highly effective against both the targeted ectoparasites and the targeted endoparasites. Applicant also asserts that Huet et al. does not teach that a composition containing 0.1% ivermectin alone is effective for their intended use.

12. The reference of Huet et al. was not used to teach of a composition containing ivermectin alone. Huet et al. was used to teach ivermectin of a concentration of 0.1%.

13. Pearlman et al. teaches that ivermectin in a concentration from about 0.25% to about 2.5% may be contained in a composition with a pediculostatic agent (i.e. commercially available product, such as cleansers, lotions, moisturizers, etc.).

14. Therefore, at the time of the invention it would have been obvious to one skilled in the art to utilize the ivermectin of concentration of 0.1% as taught by Huet et al. for the composition of Pearlman et al. as the concentrations of Pearlman et al. are from about 0.25% which does not exclude 0.1%. The instant claims also recite the concentration of ivermectin is from **about** 0.05 to **about** 0.1% or **about** 0.075%.

Conclusion

15. No claims are allowed at this time.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618